

AMENDMENTS TO THE DRAWINGS:

Transmitted herewith for the above-referenced application, please find enclosed the formal Drawings for all pending Figures, Nos. 1-15, as provided on the 12 (twelve) Sheets. Figures 7 and 8 (sheet No. 6 of 12) is provided with the following additional reference number: 22 as a communication channel. The Drawings introduce no new matter and are fully supported by the application as originally filed. For instance, the communication channel was claimed in claim nos. 50 and 51 and discussed through out the application as originally filed.

REMARKS**I. STATUS OF THE CLAIMS**

Claims 1-93 are pending in the application, of which claims 58-81 and 83-89 are withdrawn from consideration as being drawn to non-elected invention.

Claim 1 is the sole independent claim currently under examination.

Claims 3, 4 and 5 have been cancelled without prejudice herein for the sole purpose of expediting prosecution.

Claims 1-10, 14, 15, 17, 19-25, 32, 33, 34, 35-46, 50-54, 55-57, 82 and 90-93 stand rejected under 35 U.S.C. § 102.

Claims 11-13, 16, 18, 26, 27, 28, 29, 30, 31, and 47-49 stand rejected under 35 U.S.C. § 103.

II. AMENDMENTS

Base claim 1 has been rewritten to include all the limitations of dependent claims 3, 4, and 5 (of which have been cancelled herein), as well as a minor revision to the preamble.

It is believed that any amendments herein do not involve the addition of any new subject matter.

III. CLAIMS 1-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 AND 90-93 ARE NOT ANTICIPATED UNDER 35 U.S.C. § 102(b) BY SIMMET ET AL. (US. 5,961,503) BECAUSE THE APPLIED PRIOR DISCLOSE THE LIMITATIONS OF THE APPLICANTS' INVENTION.

Claims 1-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 and 90-93 were rejected under 35 U.S.C. § 102(b) as being anticipated by Simmet et al U.S. Patent No. 5,961,503 (hereinafter "Simmet"). In particular, the Office Action states:

With respect to claim 1: Simmet discloses a device for collecting boar semen. The device comprises a chamber defined by bag 20, said chamber 20 comprising a distal end, a proximal end, and a conduit

extending between said distal end and proximal end (Fig. 4). The proximal end has a rim defining an aperture and said distal end having a surface that encloses said conduit. (Fig. 3) At least a portion of said conduit proximal to said proximal end has a tapered shape radially inward defining a tapered section, whereby said tapered section accommodates a boar's penis. (Col. 4, lines 40-42) At least a portion of said conduit proximal to said distal end, specifically at seam 30 is adapted for receiving the semen ejaculated from the boar's penis (Fig. 4). The receiving portion, as can be seen in Fig. 4, defines a reservoir section for the semen.

With regard to the limitations "a device for collecting semen received from a glans penis of a male human individual", "whereby said tapered section accommodates the head of the glans penis" and "adapted for receiving the semen ejaculated from the glans penis", the device of Simmet meets all of the structural limitations of claim 1 as to collection of semen from a mammal (i.e. a boar), and thus is fully capable of collecting semen from the glans penis of a human male, and the tapered section of the device is considered herein to accommodate the head of said glans penis, and the receiving portion of the device of Simmet as claimed is considered herein to be adapted for receiving semen ejaculated from said glans penis, as the device disclosed by Simmet collects another type of mammalian semen..

(See Office Action, par. 5, pages 3-4)

The Office Action further states:

With respect to claim 2: The tapered accommodation section disclosed by Simmet meets the claim limitation as to a portion near the proximal end that is tapered radially and also accommodates the penis of a mammal, and is thus configured to the general external image of the head of a glans penis, as the structural features of such general external image are not explicitly claimed by applicant.

(See Office Action, par. 5, page 4)

The Office Action further states:

With respect to claim 3: meets the claim limitation as to a portion near the proximal end that is tapered radially and also accommodates the penis of a mammal, and is thus configured to prevent loss of any fractions of semen during ejaculation.

(See Office Action, par. 5, page 4)

The Office Action further states:

With respect to claim 4: The reservoir section disclosed by Simmet is bounded by the two rectangular segments 26,28 and seam 30 (Fig. 2) and is thus configured to prevent loss of any fractions of semen during ejaculation.

(See Office Action, par. 5, page 5)

The Office Action further states:

With respect to claim 5: The reservoir section disclosed by Simmet is bounded by the two rectangular segments 26,28 and seam 30 (Fig. 2) and is thus configured to prevent loss of any fractions of semen during ejaculation.

(See Office Action, par. 5, page 5)

Applicants respectfully traverse the rejection of claims 1-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 and 90-93 as being anticipated by Simmet because the applied prior art fails to teach or suggest the following Applicant's invention:

i) A device for collecting complete semen sample received from a glans penis of a male human individual, said device including a conduit, as recited in amended base claim 1, which calls for:

 said tapered accommodation section is configured to prevent loss of any fractions of semen during ejaculation; and/or

 said reservoir section is configured to prevent loss of any fractions of semen during ejaculation.

Base claim 1 has been rewritten to include all the limitations of dependent claims 3, 4, and 5; and accordingly Simmet fails to disclose any of the limitations as were disclosed in claims 3, 4 and/or 5. Regarding the design of the Simmet bag 20 and filter 24, Simmet neither functions nor provides the structure to prevent loss of any fractions of semen during

ejaculation and/or prevent loss of any fractions of semen during ejaculation as recited in the Applicant's base claim.

Said differently and by way of background, as stated in the specification at page 8, lines 24-30,

Loss of initial fractions may significantly affect semen analysis values, particularly sperm count and motility of a semen sample. Therefore, it is very important to recover the entire ejaculate, specially the sperm rich initial epididymal fluid fractions for sample evaluation despite the manner of collection. Unfortunately, however, no single device is available that prevents loss of semen samples during sample collection and thus optimizes semen collection and subsequent testing.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

Said differently and by way of background, as stated in the specification at page 11, lines 17-30,

Some of the advantages of some of the embodiments of the present invention semen collection and storage device, and related method of use are multifold. For example, but not limited thereto, freshly ejaculated human semen is a heterogeneous mixture of fluid and gel phases that entrap spermatozoa in a relatively immotile state before liquefaction. During ejaculation, human semen is produced in split fractions which follow a specific sequence of emission with the orgasmic contractions. The initial fractions are contributed by the Cowper's secretion followed by highly sperm rich epididymal secretions and some prostate secretion, followed by fractions containing mixture of prostatic and seminal vesicular secretions and finally the ejaculate culminates with soft gel-like coagulum primarily contributed by seminal vesicular secretion. The various embodiments of the collection device eliminate the unesthetical condom use during masturbation, prevents loss of sperm rich initial fractions during conventional collection into a test tube or into a bottle and also avoids multiple transfer related sample loss following ejaculation into a condom.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

Said differently and by way of background, as stated in the specification at page 13, lines 15-19,

Following ejaculation, the collection device 11 allows spontaneous (or subsequent) liquefaction and complete recovery of ejaculated material, provides the measurement of the ejaculated volume, provides for the mixing of sperm and liquefied seminal plasma components for subsequent semen analysis and cryo-preservation of the sample.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

In view of the differences of base claim 1 and Simmet, Applicants respectfully urge that the rejections of claims 1-10, 14, 15, 17, 19-25, 32, 35-46, 55-57 and 90-93 be withdrawn.

IV. CLAIMS 1, 33, 34, 50-54 ARE NOT ANTICIPATED UNDER 35 U.S.C. § 102(b) BY FLEURY (US . 5,569,225) BECAUSE THE APPLIED PRIOR DISCLOSE THE LIMITATIONS OF THE APPLICANTS' INVENTION.

Claims 1, 33, 34, 50-54 and 82 were rejected under 35 U.S.C. § 102(b) as being anticipated by Fleury U.S. Patent No. 5,569,225. In particular, the Office Action states:

With respect to claim 1: Fleury discloses a device for collecting semen received from a glans penis of a male human individual. The device comprises a chamber 14, said chamber comprising a distal end, a proximal end, and a conduit extending between said distal end and proximal end. The proximal end has a rim defining an aperture. (Fig. 1) The distal end has a surface adjacent valve 23 that is sealed to the lower end 16 of chamber 14 that encloses said conduit. (Col. 5, lines 25,26) At least a portion of said conduit proximal to said proximal end has a tapered shape radially inward defining a tapered section, whereby said tapered section accommodates female genitalia and thus is considered herein to be able to accommodate the head of the glans penis. (Col. 5, line 66 - Col. 6, line 5) At least a portion of said conduit proximal to said distal end 16 is adapted for receiving the semen ejaculated from the glans penis, said receiving portion defining a reservoir section for the semen. (Col. 5, lines 36-41).

(See Office Action, par. 7, page 11)

Applicants respectfully traverse the rejection of claims 1, 33, 34, 50-54 and 82 as being anticipated by Fleury because the applied prior art fails to teach or suggest the following Applicant's invention:

i) A device for collecting semen received from a glans penis of a male human individual, said device including a conduit, as recited in amended base claim 1, which calls for:

 said tapered accommodation section is configured to prevent loss of any fractions of semen during ejaculation; and/or

 said reservoir section is configured to prevent loss of any fractions of semen during ejaculation.

Base claim 1 has been rewritten to include all the limitations of dependent claims 3, 4, and 5; and accordingly Fleury fails to disclose any of the limitations as were disclosed in claims 3, 4 and/or 5. Regarding the design of the Fleury chamber 14 and collection bag, Fleury neither functions nor provides the structure to prevent loss of any fractions of semen during ejaculation and/or prevent loss of any fractions of semen during ejaculation as recited in the Applicant's base claim.

Said differently and by way of background, as stated in the specification at page 8, lines 24-30,

 Loss of initial fractions may significantly affect semen analysis values, particularly sperm count and motility of a semen sample. Therefore, it is very important to recover the entire ejaculate, specially the sperm rich initial epididymal fluid fractions for sample evaluation despite the manner of collection. Unfortunately, however, no single device is available that prevents loss of semen samples during sample collection and thus optimizes semen collection and subsequent testing.

Accordingly, Simmet fails to suggest or teach the present invention as claimed and taught in the specification.

Said differently and by way of background, as stated in the specification at page 11, lines 17-30,

 Some of the advantages of some of the embodiments of the present invention semen collection and storage device, and related method of use are multifold. For example, but not limited thereto, freshly ejaculated human semen

is a heterogeneous mixture of fluid and gel phases that entrap spermatozoa in a relatively immobile state before liquefaction. During ejaculation, human semen is produced in split fractions which follow a specific sequence of emission with the orgasmic contractions. The initial fractions are contributed by the Cowper's secretion followed by highly sperm rich epididymal secretions and some prostate secretion, followed by fractions containing mixture of prostatic and seminal vesicular secretions and finally the ejaculate culminates with soft gel-like coagulum primarily contributed by seminal vesicular secretion. The various embodiments of the collection device eliminate the unesthetic condom use during masturbation, prevents loss of sperm rich initial fractions during conventional collection into a test tube or into a bottle and also avoids multiple transfer related sample loss following ejaculation into a condom.

Accordingly, Fleury fails to suggest or teach the present invention as claimed and taught in the specification.

Said differently and by way of background, as stated in the specification at page 13, lines 15-19,

Following ejaculation, the collection device 11 allows spontaneous (or subsequent) liquefaction and complete recovery of ejaculated material, provides the measurement of the ejaculated volume, provides for the mixing of sperm and liquefied seminal plasma components for subsequent semen analysis and cryopreservation of the sample.

Accordingly, Fleury fails to suggest or teach the present invention as claimed and taught in the specification.

Moreover, Applicants respectfully traverse the above-referenced characterizations as the Office Action fails to correlate the applied references to the claimed elements. Applicants respectfully submit that the *prima facie* case of anticipation and obviousness has neither been presented nor achieved by the Office Action. Applicants submit that the applied references are not accurately interpreted by the Examiner.

MPEP §2131 provides:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d

1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim.

For example, the Office Action fails to recite any support where the Fleury accomplishes Applicant's base claim elements cited above. For instance, Fleury fails to make any reference to semen or glans penis as recited in the office action, but rather a tapered section corresponding to the exterior of a female and for urine (for example: col. 5, lines 16-24 and col. 6, lines 1-5).

In view of the differences of base claim 1 and Fleury, Applicants respectfully urge that the rejections of claims 1, 33, 34, 50-54 and 82 be withdrawn.

Summary

In summary, Simmet and Fleury (and the applied prior art) fails to teach the Applicant's invention as claimed in amended base claim 1. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for the collection of the complete split ejaculates and entire semen sample. As loss of semen fractions during initial or later collection phase of ejaculation results in substantial errors in sperm count and sperm motility values. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for the complete semen liquid fraction and coagulum fraction collection and subsequent liquefaction of entire ejaculate in the collection device. For instance, unlike Simmet and Fleury (and the applied prior art), Applicant's invention allows for the accurate collection of all harvested components. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for the liquefaction of all fractions of ejaculation and sperm count, morphology and motility determination that can be made for the optional recovery for successful intrauterine insemination and in vitro fertilization support to subfertile couples. For instance, unlike Simmet and Fleury (and the applied prior art), the Applicant's invention allows for a defined aliquot of the semen that may be withdrawn in order to determine accurate sperm concentration.

V. CLAIMS 11-13 AND 18 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET, CLAIM 16, 26 AND 27 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW OF BAR-ARMI (US 6,129,214), CLAIM 30 AND 31 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW OF ERICSSON ET AL. (US 5,068,089), CLAIM 47-49 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW OF YAP (US 6,113,532), AND CLAIMS 28 AND 29 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER SIMMET IN VIEW VELAZQUEZ (US 6,699,226) BECAUSE THE APPLIED PRIOR ART AS A WHOLE FAILS TO SUGGEST THE APPLICANTS' INVENTION.

Claims 11-13 and 18 are patentable under 35 U.S.C. § 103 over Simmet, claim 16, 26 and 27 are patentable under 35 U.S.C. § 103 over Simmet in view of Bar-Armi (us 6,129,214), claim 30 and 31 are patentable under 35 U.S.C. § 103 over Simmet in view of Ericsson et al. (us 5,068,089), claim 47-49 are patentable under 35 U.S.C. § 103 over Simmet in view of Yap (us 6,113,532), and claims 28 and 29 are patentable under 35 U.S.C. § 103 over Simmet in view Velazquez (US 6,699,226) because the applied prior art as a whole fails to suggest the Applicants' invention.

Applicants respectfully submit that claims 11-13, 16, 18, 26, 27, 28, 29, 30, 31, and 47-49 would not have been obvious over Simmet, Bar-Ami, Ericsson, Yap, or Velazquez because the applied prior art fails to teach or suggest the present invention.

The Examiner's reliance on Simmet, Bar-Ami, Ericsson, Yap, or Velazquez does not supply the deficiencies of the disclosures regarding the dependent claims vis-à-vis Applicants' base claim 1. A dependent claim contains all the limitations of the intermediate claim upon which it depends and is non-obvious under Federal Circuit guidelines if the intermediate claim upon which it depends is allowable. Hence, it is the Applicants' position that the cited art as whole fails to teach or suggest the claimed invention within the meaning of 35 U.S.C. § 103 and request that the rejection of dependent claims 11-13, 16, 18, 26, 27, 28, 29, 30, 31, and 47-49 be withdrawn.

VI. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that claims 1-93, are in condition for allowance, and a notice for allowance is solicited.

Should questions arise during examination, the Examiner is welcome to contact the Applicants' attorney at the telephone listed below.

Please charge any excess fees due and credit any overpayment to Charge Account No. 50-0423.

Respectfully submitted,

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